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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,666	04/04/2006	Mannalal Ramgopal Bajaj	125139-00101	9001

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EXAMINER	
LEA, CHRISTOPHER RAYMOND	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
09/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,666	BAJAJ ET AL.	
	Examiner	Art Unit	
	Christopher R. Lea	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-10,12 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-10,12 and 16-18* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 (national stage application) of PCT/IN04/00342.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2009, has been entered.

Receipt of Amendments/Remarks filed on September 2, 2009, is acknowledged. In response to Final office action dated June 29, 2009, and the interview of July 31, 2009, applicant amended claims 1, 10, & 17 and added no new claims. Claims 1, 7-10, 12, & 16-18 are pending. Claims 1, 7-10, 12, & 16-18 are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

1. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 recites that the pH

of the system be 9-11, which is a limitation already claimed by claim 1, from which claim 8 depends; hence, claim 8 does nothing to narrow the scope of the invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 depends on canceled claim 5; therefore, the claim is necessarily indefinite. The examiner will treat the claim as though it depended from claim 1, and it would be remedial to amend the claim so that it depended from a pending claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 7-10, 12, & 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doen et al. (US PreGrant Publication 2003/0191157).

Applicant claims

Applicant claims a drug delivery system containing rabeprazole sodium, mannitol, an alkaline compound and water for injection. Applicant further teaches a method of making such a system.

Determination of the scope and content of the prior art (MPEP 2141.01)

Doen et al. teach, as a whole, an injectable composition containing a benzimidazole.

Claims 1, 7, & 8: Doen et al. teach an injectable composition containing a benzimidazole compound and an alkaline compound in a molar ratio of about 1:1 (paragraph 35). Doen et al. teach rabeprazole sodium among the benzimidazole compounds suitable for use in the injectable composition (paragraph 76). Doen et al teach that sodium hydroxide is the preferred alkaline compound suitable for use in the injectable composition (paragraph 86). Doen et al. teach that a saccharide may be added to the composition as an excipient and that mannitol is the preferred excipient suitable for use in the injectable composition (paragraph 91). Doen et al. teach water for injection as a solvent for dissolving (paragraph 99) or redissolving (paragraph 110) the composition. Doen et al. teach the pH of the composition as about 9 to 11 in physiological saline (paragraph 99).

Claims 9 & 16: Doen et al. teach a composition that contains ~29% benzimidazole compound (Example 3, Table 4, paragraph 132).

Claims 10 & 17: Doen et al. teach a composition that contains ~58% excipient (Example 3, Table 4, paragraph 132).

Claims 18 & 12: Doen et al. teach adding a benzimidazole compound and mannitol to a sodium hydroxide solution and adding water for injection (paragraph 128, changing the order of adding ingredients is *prima facie* obvious, MPEP § 2144.04.IV.C). Doen et al. teach rabeprazole sodium among the benzimidazole compounds suitable for use in the injectable composition (paragraph 76). Doen et al. teach sterile filtering the solution (through 0.22 micron filter) and placing it in vials (paragraphs 128-9). Though Doen et al. are silent as to the exact size of the vial and its sterility, they teach the vial

size is under 20 mL (paragraph 106) and it would have been obvious to a skilled artisan to put a sterile filtered solution into a sterile vial and bunging the vial to maintain sterility. Doen et al. are silent as to the temperature at which the steps are carried out; however, the maintaining a constant temperature is within the purview of the skilled artisan. Doen et al. teach lyophilizing the solution to form a powder (paragraph 132). The resultant composition meets the limitations of claim 12.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings of Doen et al. and the instant claims is that Doen et al. do not exemplify an embodiment of the invention using rabeprazole sodium as the benzimidazole and do not teach the claimed molar ratio.

Finding of *prima facie* obviousness Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use rabeprazole sodium as the benzimidazole and adjust the molar ratio of alkaline to rabeprazole sodium and produce the instant invention. The skilled artisan would have been motivated to use rabeprazole sodium as the benzimidizole because Doen et al. teach that it is suitable for that use and it is within purview of the skilled artisan to select a known material based on its suitability for its intended use. Reading a list and selecting a known compound to meet known

requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle (see MPEP § 2144.07). The skilled artisan would have been motivated to adjust the ratio of rabeprazole sodium to alkaline compound because Doen et al. although the preferred ratio is 1:1, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is not inventive to discover the optimum or workable ranges by routine experimentation when the prior art discloses the general conditions of a claim (See MPEP 2144.05 II).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in using rabeprazole sodium as the benzimidazole and adjusting the molar ratio of alkaline to rabeprazole sodium and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Response to Arguments

8. Applicant's arguments filed September 2, 2009, have been fully considered but they are not persuasive.

Applicant argues that the ratio of benzimidazole to alkali taught by Doen et al. is crucial to resolve the problems with previous injectable compositions containing benzimidazole, hence one of ordinary skill in the art would not be motivated to change the ratio. This not found convincing because the problem that Doen et al. seek to overcome is the irritation associated with the high alkali content of previous compositions (paragraph 9). This teaching alone provides motivation for lowering the alkali content (and thereby lowering the ratio). Additionally, as the examiner has stated above differences in concentration are not generally supportive of patentability in the absence of evidence of a secondary consideration.

Applicant further argues that the pH would change as the amount of alkaline compound was decreased; however, the claims do not exclude possibility of non-alkaline compound pH adjusters, e.g. a buffer (paragraphs 90 & 95), being used to maintain the pH at a desired level.

In the interview on July 31, 2009, the parties agreed that the above rejection might be overcome by a showing of an unexpected result related to the claimed ratio. The examiners were clear, however, that such a showing must be supported by factual evidence (i.e. a declaration). In the response dated September 2, 2009, applicant has merely presented arguments and not evidence. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need,

inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant (MPEP §706.01(c) II).

The expected result remains the same, an injectable rabeprazole composition is made in the absence of evidence to the contrary. No unexpected results have been presented. Applicant's arguments are not persuasive, and the rejection under 35 U.S.C. §103(a) is maintained

Prior Art made of Record

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,536,735 teaches injectable benzimidazole compositions.

Conclusion

Claims 1, 7-10, 12, & 16-18 are rejected. Claim 8 is objected to. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Fri 8:00-4:30 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616